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Gamp 5 spreadsheet validation

What is the difference between gamp 4 and gamp 5. Gamp spreadsheet validation. Gamp 5 validation. Gamp 5 document list. What is gamp 5.

Spreadsheets have diverse applications in the GxP environment, serving as calculators, timesheets, bills of material, forms, and databases. However, standard spreadsheet applications are not designed for GxP compliance, posing several risks. I once underestimated these risks, which led to punishment from the auditor. After this experience, I learned the importance of classification in dealing with spreadsheets. The complexity level of the spreadsheet is a crucial factor in determining the methodology to be used. According to GAMP 5 for End User Application, Category 1 uses Microsoft Excel or Access, while Category 3 employs simple arithmetic calculations and printing functions without custom VBA modules. Category 4 involves complex spreadsheets with limited statistical functions and Category 5 contains spreadsheets with custom macros, sophisticated databases, and combined boolean functions. After classification, it's essential to assess the impact of these risks on the quality system, taking additional measures when risk is high and doing less when risk is low. The process of validation and operation strategy for each category will be discussed in a future update. To ensure computerized systems in the environment comply with requirements, spreadsheets also need validation. However, controls may be inadequate, leading to compliance risks. When it comes to validating spreadsheets, custom code-containing spreadsheets require verification for correctness. Formulas and algorithms should be checked for accuracy. Templates must have suitable controls to prevent erroneous calculations from previous data. Version control and accurate storage are crucial. For accuracy checks, data integrity is key. Files and calculations should be secured to prevent accidental overwriting or incorrect input. Spreadsheets are widely used in the pharmaceutical industry for tasks like analytical calculations, asset management, unique ID generation, training records, and reporting. However, unvalidated spreadsheets can create compliance issues when generating regulated reports or making scientific decisions. To address this, it's essential to replace unvalidated spreadsheets with a validated process, such as Excel Spreadsheet Validation. This replacement process can be manual but less efficient or replaced with IT solutions that require validation. When implementing IT solutions like Laboratory Information Management Systems (LIMS), companies must adapt their processes and train employees to operate within the new system. A notable truth about IT solutions is that they can be tailored in various ways, but once deployed, significant changes are often challenging. Unlike spreadsheets, which can evolve alongside a company's growth and changes, IT solutions may become outdated before deployment. To mitigate this, companies should validate all spreadsheets used for regulated reports or critical decisions. This process can involve identifying hundreds of spreadsheets, making validation and maintenance a substantial undertaking. Option 2 necessitates validating an extensive suite of spreadsheets, which must remain in a validated state and be capable of rapid updates to support business changes. Addressing this challenge one spreadsheet at a time is impractical due to costs and time constraints. To succeed, companies need a comprehensive spreadsheet validation solution that can handle a large number of spreadsheets efficiently. A typical deployment for compliant spreadsheets involves maintaining templates in a controlled environment, with templates progressing through a defined lifecycle from "Active" or "Verified" status to "Inactive" when superseded or no longer required. Template verification is an optional step where calculations and automation are documented and tested, producing a "Verified" template. This process can help companies avoid lengthy document reviews by choosing which templates to verify based on usage frequency and complexity. In a compliant environment, verifying spreadsheet content is mandatory, either at the upfront stage of template creation or during each document review. Within a safe and controlled environment, changes to documents must be tracked in an audit trail, with signatures required from authors, reviewers, and approvers. Several solutions can provide the necessary control for templates and documents, categorized into three main types: 1. **From Scratch**: A combination of operating procedures and access-controlled file shares. 2. **Tool Kit**: Software-based file sharing platforms like SharePoint or Dropbox. 3. **Vendor Solution**: A targeted solution specifically designed to ensure spreadsheet compliance. The "Vendor Solution" is highly recommended unless a company has extensive experience in this area and can dedicate the necessary time and resources. In-house development, even with advanced tools, faces challenges due to the flexibility inherent in spreadsheets. The principles of file security and compliance are straightforward but bringing the wide-ranging functionality of spreadsheets under control requires experience. The goal is to bring spreadsheets into compliance rather than starting a research project. Validation should be separated into two components: 1. **Environment Validation**: Ensuring the environment where Templates and Documents are secured. 2. **Spreadsheet Validation Packages**: Validating each spreadsheet individually, expected to grow with business needs. Separating these components allows for easier maintenance of the solution. The validation process involves a series of documents, including: - **Item Description** - **Validation Master Plan** - **User Requirements** and **High Level Business Requirements** - **System Requirements**, with specifications denoted by an asterisk (*). - **Functional Requirements Specification**, detailing how the system meets user needs. - **Design Specification**, outlining the technical definition of the system. - **Installation Qualification**, documenting successful installation. The report provides a summary of the solution's functionality, risk assessment, and performance qualification. The testing executed to prove the solution's expected operation is documented. Risk Assessment considers how the solution fits into the business environment, identifying potential risks that may arise. This involves categorizing spreadsheets based on impact and complexity according to GAMP 5 guidelines. The report highlights the importance of assigning a single category for all templates to simplify documentation management. Categorizing individual templates avoids full documentation sets for simpler templates, but this approach is not overly complex due to easy documentability. GMP Category 5 documentation includes a Validation Plan defining the template lifecycle and requirements, functionality, and design considerations. The plan also outlines calculations, alert criteria, number of decimals displayed, automation deployed, data validation options, and significant format. The report emphasizes the importance of Traceability between requirements and testing, with a Test Plan outlining defined testing and predetermined acceptance criteria. A Test Report documents testing performed, while a Validation Report summarizes the validation exercise, including previous template versions and testing performed on each version. The template revision process should be defined in the "Validation Plan" with a risk-based strategy for regression testing. A typical documentation set includes: * Required Changes and Risk Assessment: defining required changes and assessing against criteria * Test Plan: outlining testing and predetermined acceptance criteria * Test Report: documenting testing performed * Traceability: between requirements and testing Summarizing Validation Results and Template Evolution